

REMARKS

This Request for Continued Examination (RCE) is filed under 37 C.F.R. § 1.114. This RCE is being filed prior to the abandonment of the application, as the Notice of Appeal filed under 37 C.F.R. § 1.191 on January 26, 2006 sets a two-month period for response. The amendments to the claims that have not been previously entered and the arguments regarding patentability applicable to the claims as amended constitute the submission required for an RCE under 37 C.F.R. § 1.114(c). The fee for a RCE under 37 C.F.R. § 1.17(e) of \$395.00 accompanies this RCE.

Claims 1-51 are currently pending in the above-identified application and remain for consideration. Claims 50-51 are added by this amendment and were not present in the amendment of January 26, 2006.

In the Advisory Action mailed February 16, 2006, the Examiner indicated that the previously filed amendment would not in fact be entered in the event of an appeal. Accordingly, the amendments to the claims presented herewith include the amendments originally submitted on January 26, 2006 but not entered, and the references to claims being currently amended or previously presented are the same as in the amendment submitted January 26, 2006. However, new claims 50-51 are added by this amendment and were not present in the amendment of January 26, 2006.

Claims 1-51 are pending in the above-identified application and remain for consideration.

Claims 1-8, 14-15, 17-24, 30, 36-43, 45-46, and 48 were rejected under 35 U.S.C. § 102(b) as anticipated by C.H. Chung et al., "An Improved Method for Isolating High Quality Polysaccharide-Free RNA from Tenacious Plant Tissues," Mol. & Cells 6: 108-111 (1996) ("Chung et al. (1996)").

Claims 1-6, 8-9, 14-16, 37-41, and 43-47 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 95/35390 by Zhang (“Zhang ‘390”).

Claims 1-6, 8-9, 14-22, 24-25, 31-41, and 43-44, and 46-48 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 93/03167 by Sigman et al. (“Sigman et al. ‘167”).

Claims 1-3, 6, 10-19, 22, 26-32, and 34-36 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,168,922 to Harvey et al. (“Harvey et al. ‘922”) as defined by A Akane et al., “Identification of the Heme Compound Copurified with Deoxyribonucleic Acid (DNA) from Bloodstains, a Major Inhibitor of Polymerase Chain Reaction (PCR) Amplification,” Forensic Sci. 39: 362-372 (1994) (“Akane et al. (1994)”). Claims 1-3, 10, 12-19, 22, 26, 28-32, and 34-36 were also rejected under 35 U.S.C. § 102(a) as anticipated by Harvey et al. ‘922 as defined by Akane et al. (1994).

Claims 7 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Harvey et al. ‘922.

Claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Chung et al. (1996), Sigman et al. ‘167, or Harvey et al. ‘922 (in the alternative) each in view of Ahern, The Scientist 9: 1-5 (1995) (“Ahern (1995)”).

Claims 1-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,548,546 to Baker (“Baker ‘546”).

Claims 17-36 and 48 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker ‘546 in view of Sigman et al. ‘167.

Claim 49 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Ahern (1995).

Claim 49 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of copending Application Serial No. 11/138,543 ("the '543 Application").

Claim 49 was also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-13 and 17-18 of the '543 Application in view of Ahern (1995).

Reexamination of the application as amended in the RCE, reconsideration of the rejections, and allowance of the claims remaining for consideration are respectfully requested.

The two-month shortened statutory period subsequent to the Notice of Appeal expires on March 26, 2006. Accordingly, this RCE is being filed in a timely manner.

#### I. AMENDMENTS TO THE APPLICATION

Entry of the amendments to the application is respectfully requested. As detailed below, these amendments introduce no new matter.

The specific masking agents recited in the independent claims, claims 1, 17, 37, and 49, are supported by the specification at page 5, lines 23-27.

The specific assays recited in newly presented claims 50-51 are supported by the specification at page 5, lines 18-22

This response is being filed in accordance with recently revised 37 C.F.R. § 1.121, as set forth in 68 F.R. 38611 (June 30, 2003). If the amendment is considered to be not in compliance with recently revised 37 C.F.R. § 1.121, the Examiner is respectfully requested to contact the undersigned at her earliest possible convenience.

Accordingly, entry of the amendments to the claims is respectfully requested.

## II. THE REJECTIONS UNDER 35 U.S.C. § 102

### A. The Rejection of Claims 1-8, 14-15, 17-24, 30, 36-43, 45-46 and 48 Under § 102(b) as Anticipated by Chung et al. (1996)

Claims 1-8, 14-15, 17-24, 30, 36-43, 45-46, and 48 were rejected under 35 U.S.C. § 102(b) as anticipated by C.H. Chung et al., "An Improved Method for Isolating High Quality Polysaccharide-Free RNA from Tenacious Plant Tissues," Mol. & Cells 6: 108-111 (1996) ("Chung et al. (1996)").

To the extent that the amendments of claim 1, 17, and 37 have not obviated this rejection, it is respectfully traversed.

With respect to claims 1-8 and 14-15, Chung et al. (1996) does not teach the suppression of interference by a masking agent. The claims specifically require this result (see claim 1). There is no discussion of any of the masking agents contemplated in the present application. The extraction of RNA from samples of pulverized sesame or perilla oilseeds does not inherently involve freeing the RNA from masking agents of the type recited in the claims of the present application, including claim 1. Specifically, there is no teaching in Chung et al. (1996) or anywhere else that pulverized sesame or perilla

oilseeds contain significant quantities of the masking agents recited explicitly in the independent claims as amended.

In particular, Chung et al. (1996) is directed to the removal of polysaccharides or phenolic compounds from RNA being isolated from plant materials, particularly oilseeds. For example, at p. 109, second column, lines 41-43, the process of Chung et al. (1996) is directed as being “highly effective in differentially precipitating polysaccharides from the final RNA preparations.”

The suppression of interference by a masking agent as recited in the specification and claims of the present application, as distinguished from possible interference caused by polysaccharides and phenolic compounds, cannot be said to be inherent in the disclosure of Chung et al. (1996). Inherency cannot be established by probabilities or possibilities. Continental Can Co. USA v. Monsanto Co., 20 U.S.P.Q. 2d 1746 (Fed. Cir. 1991). To support an anticipation rejection based on inherency, as the rejection of claims 1-8 and 14-15 appears to be, the Examiner must provide factual and technical grounds establishing that the inherent feature necessarily flows from the teachings of the prior art. Ex parte Levy, 17 U.S.P.Q. 2d 1461, 1464 (Bd. Pat. Off. App. & Int’f 1990). This is lacking here, particularly in view of the failure of Chung et al. (1996) to recite masking agents that are identical to or even analogous with those recited in the claims of the present application. Polysaccharides and phenolic compounds have different solubilities from the masking agents recited in the pending claims and thus there is no expectation that they would behave similarly in either the extraction procedures or subsequent assays.

With regard to claims 17-24, 30, and 36, there is no disclosure in Chung et al. (1996) of “suppressing the interference of a masking agent on a molecular assay of a nucleic acid-containing test sample” as required by these claims. The demonstration of “enhanced absorbance ratios” is not sufficient to show that interference from a masking agent has been suppressed. This is particularly true in view of the difference in chemical

properties between the masking agents recited in the claims of the present application and the polysaccharides and phenolic compounds recited in Chung et al. (1996)

What is demonstrated by “enhanced absorbance ratios” is the freedom of the nucleic acid preparation from protein contamination, as the  $A_{260}/A_{280}$  ratio of a nucleic acid preparation is roughly indicative of the degree of protein contamination of the nucleic acid preparation. This is well known in the art, as nucleic acids (both DNA and RNA) absorb ultraviolet light strongly with a peak at 260 nanometers, while proteins absorb ultraviolet light with a peak at 280 nanometers. However, the absorbance ratio is at best a crude indication of purity and cannot, by itself, be taken to indicate suppression of interference from a potential masking agent. Additionally, even the efficacy of the method of Chung et al. (1996) is impossible to judge solely on the basis of the  $A_{260}/A_{280}$  ratio.

With regard to claims 37-43, 45-46, and 48, there is no teaching in Chung et al. (1996) of improving hybridization of nucleic acids. The “signal response” of Figure 2 of Chung et al. (1996) cannot be said to relate to improved hybridization, and there is no basis for concluding from Chung et al. (1996) that the method of Chung et al. (1996) actually improved the hybridization or improved the performance of Northern blotting, in which RNA is separated by electrophoresis and hybridized to labeled DNA. The demonstration of intact and functional cDNA does not necessarily and inevitably lead to the conclusion that hybridization has been improved, as there is no comparison with the hybridization of cDNA that was isolated by other means. Thus, the limitation of the claims that recite “improving hybridization of nucleic acids” is not met by the teachings of Chung et al. (1996).

It is inappropriately broad to consider the term “molecular assay” to be “any assay involving DNA,” as suggested in the Office Action. It is clear from the examples given at lines 17-22 of page 5 of the specification that “molecular assay” is intended to include only assays in which there is sequence-specific recognition of the DNA either by a protein or by another nucleic acid. A simple assay of the quantity of

DNA by measurement of  $A_{260}$ , for example, would not properly be construed as a molecular assay in light of the specification, because there is no sequence-specific recognition of any sequence within the DNA molecule. Notwithstanding In re Van Geuns, 26 U.S.P.Q. 2d 1057 (Fed. Cir. 1993), one of ordinary skill in the art would draw an inference from the examples of molecular assays given in the specification that these assays require sequence-specific recognition of the DNA.

For clarification, specific assays are recited in claims 50 and 51.

Even the generation of clearer bands on agarose gel electrophoresis cannot be read as equivalent to improved performance in molecular assays. Many factors, including the ionic strength of the solution used in the gel electrophoresis procedures and the presence of proteins or other components that do not interfere in sequence-specific molecular assays, can lead to smearing or spreading out of bands in gel electrophoresis. The generation of clearer bands on agarose gel electrophoresis cannot therefore be equated to suppression of the activity of masking agents.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

B. The Rejection of Claims 1-6, 8-9, 14-22, 24-25, 31-41, 43-44, and 46-48 Under 35 U.S.C. § 102(b) as Anticipated by Sigman et al. '167

Claims 1-6, 8-9, 14-22, 24-25, 31-41, 43-44, and 46-48 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 93/03167 by Sigman et al. ("Sigman et al. '167").

To the extent that the amendment of claim 1, 17, and 37 has not obviated this rejection, it is respectfully traversed.

The teachings of Sigman et al. '167 are directed to methods of isolating and preserving DNA, specifically DNA associated with parasites such as *Trypanosoma cruzi*.

With respect to claims 1-6, 8-9, 14-22, 24-25, and 30-36, Sigman et al. '167 does not disclose or suggest the suppression of interference by a masking agent or the improvement of a signal response in a molecular assay due to the suppression of interference by a masking agent. The masking agents recited specifically in these claims as amended are not disclosed by Sigman et al. '167.

Sigman et al. '167 is actually directed to the use of conditions in which controlled cleavage of the highly catenated closed circular DNA of parasites such as *T. cruzi* can be accomplished. If there is suppression of interference by a masking agent or the improvement of a signal response in a molecular assay, it is strictly inadvertent and unintentional. This is particularly true in light of the fact that the masking agents recited in the independent claims of the present application, as amended, are not disclosed in Sigman et al. '167.

It is well-established in patent law that unintended anticipation is not anticipation. Tilghman v. Proctor, 102 U.S. 707 (1881). If the work of Sigman et al. '167 creates suppression of interference by a masking agent or the improvement of a signal response in a molecular assay due to suppression of interference by a masking agent, it is unintended and is not inherent in the methods disclosed by Sigman et al. '167. In other words, there is no teaching in Sigman et al. '167 of suppression of interference by a masking agent or improvement in a signal produced by a molecular assay.

The term "molecular assay" must, in light of the specification of the present application, be read to mean a molecular assay in which sequence-specific recognition, either between two nucleic acids or between a nucleic acid and a protein, plays some role. The chemical cleavage optimized in Sigman et al. '167 is not encompassed by this definition. The chemical cleavage does not involve sequence-



specific recognition either between two nucleic acids or between a nucleic acid and a protein. The chemical cleavage does not involve recognition of a second nucleic acid molecule and is not catalyzed by a protein. The cleavage is catalyzed by a reagent such as a 1,10-phenanthroline-copper complex, a derivative of ferrous EDTA, or other metal-containing octahedral complexes (page 15, lines 12-25). None of these reagents includes either protein or nucleic acid or derives any specificity of its cleavage action from protein or nucleic acid. Again, for clarification, specific assays are recited in claims 50-51. There is no suggestion in Sigman et al. '167 that the reagents recited therein could be effective in reducing interference from the masking agents recited in the claims of the present application in the assays of claims 50-51.

The mere preservation of DNA for future use does not in and of itself establish that the DNA is preserved in a condition in which the specific masking agents recited in the claims of the present application are eliminated or suppressed. Unless this is done, and there is no teaching of this in Sigman et al. '167, the masking agents will interfere with a subsequent procedure such as PCR.

Again, inherency cannot be established by probabilities or possibilities. Continental Can Co., 20 U.S.P.Q. 2d at 1746. Prevention of degradation by a nuclease cannot be equated with the suppression of interference with a masking agent. Most masking agents do not act to degrade the DNA, so prevention of nuclease degradation would not in and of itself suppress interference by most masking agents.

With respect to claims 37-41 and 43-48, Sigman et al. '167 fails to teach or disclose improvement in hybridization. Again, Sigman et al. '167 is focused on methods by which the DNA is subject to chemical cleavage. There is no teaching in Sigman et al. '167 of improvement in hybridization and no discussion in Sigman et al. '167 of improvement in hybridization that can possibly be attributed to the removal or suppression of the specific masking agents recited in these claims. Again, any anticipation would be unintended and accidental, and would not be inherent in the methods of Sigman et al. '167.

The Office Action refers to the possible activity of nucleases as masking agents. This possibility is eliminated by the amendments to the claims. These amendments exclude nucleases from consideration as masking agents.

C. The Rejection of Claims 1-6, 8-9, 14-16, 37-41, and 43-47 Under 35 U.S.C. § 102(b) as Anticipated by Zhang ‘390

Claims 1-6, 8-9, 14-16, 37-41, and 43-47 were rejected under 35 U.S.C. § 102(b) as anticipated by PCT Published Patent Application No. WO 95/35390 by Zhang (“Zhang ‘390”).

To the extent that the amendment of claim 1, 17, and 37 has not obviated this rejection, it is respectfully traversed.

With respect to claims 1-6, 8-9, and 14-16, there is no teaching in Zhang ‘390 of suppressing interference by a masking agent such as those recited specifically in claim 1. The removal of unbound proteins, nucleic acids, or probes that might interfere with subsequent steps cannot be equated with the removal of a masking agent. There is absolutely no teaching or suggestion in Zhang ‘390 of the removal of a masking agent, as that term is defined in the specification and recited specifically in claim 1.

With respect to claims 37-41 and 43-47, there is again no teaching in Zhang ‘390 of improvement in hybridization of nucleic acids attributable to the removal or suppression of the specific masking agents recited in these claims. There is no teaching or suggestion in Zhang ‘390 that the “unbound proteins, nucleic acids and probes” recited at page 18, lines 10-11 of Zhang ‘390 include any of the masking agents specifically recited in these claims as the result of the amending of these claims.

The preamble must be given patentable weight as it “gives life, meaning, and vitality to the claim” and makes clear what is to be accomplished by the method steps

recited in the claim. “If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is ‘necessary to give life, meaning, and vitality’ to the claim, then the claim preamble should be construed as if in the balance of the claim.” Pitney Bowes, Inc. v. Hewlett-Packard Co., 51 U.S.P.Q. 2d 1161, 1165-66 (Fed. Cir. 1999). In the absence of any teaching in Zhang ‘390 as to what needs to be done to accomplish the goal of the method recited in these claims, there is no basis for this rejection.

Again, the masking agents are now recited specifically, which obviates this rejection.

D. The Rejection of Claims 1-3, 6, 10-19, 22, 26-32, and 34-36 Under 35 U.S.C. § 102(e) as Anticipated by Harvey et al. ‘922 as Defined by Akane et al. (1994)

Claims 1-3, 6, 10-19, 22, 26-32, and 34-36 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,168,922 to Harvey et al. (“Harvey et al. ‘922”) as defined by A Akane et al., “Identification of the Heme Compound Copurified with Deoxyribonucleic Acid (DNA) from Bloodstains, a Major Inhibitor of Polymerase Chain Reaction (PCR) Amplification,” Forensic Sci. 39: 362-372 (1994) (“Akane et al. (1994)”). Claims 1-3, 10, 12-19, 22, 26, 28-32, and 34-36 were also rejected under 35 U.S.C. § 102(a) as anticipated by Harvey et al. ‘922 as defined by Akane et al. (1994).

To the extent that the amendment of claim 1 and 17 has not obviated this rejection, it is respectfully traversed.

In the first place, there is no basis for the position taken by the Office that the prior application, Application Serial No. 09/185,402 (“the ‘402 Application”) does not provide support for the recitation of a “masking agent” in general. It is conceded that the ‘402 Application does recite hemoglobin and methemoglobin, which are typical

masking agents as that term is used in the present specification and claims. Specifically, methemoglobin is included in the pending claims.

It is well understood that not all specific examples of a compound that has a particular activity or properties be recited in the specification for there to be support for a more general recitation of a compound having such activity or properties. In re Wright, 27 U.S.P.Q. 2d 1510, 1513 (Fed. Cir. 1993) (“Nothing more than objective enablement is required, and therefore it is irrelevant whether [a] teaching is provided through broad terminology or illustrative examples.”) There is nothing in the properties of hemoglobin or methemoglobin that makes them unrepresentative examples of masking agents as that term is used in the present specification and claims.

Accordingly, priority to the ‘402 Application is appropriate and the Examiner is therefore respectfully requested to reverse this decision and award Applicant priority to the ‘402 Application.

Even if priority is not granted for the ‘402 Application with respect to the recitation of “a masking agent” in general, Harvey et al. does not teach the claimed invention because Harvey et al. ‘922 does not teach adding the required components to a “test sample” as that term is used in the specification and claims of the present application. The nucleic acid is applied to an absorbent such as a paper (e.g., claim 1 of Harvey et al. ‘922). An example is a cellulosic paper (column 3, lines 16-18). The nucleic acid must be released from the support to create a “test sample.”

The fact that heme was known to inhibit PCR reactions, as taught by Akane et al. (1994), does not make Harvey et al. ‘922 an anticipatory reference. Akane et al. (1994) tentatively identified the inhibitory component as a heme-blood protein complex. However, Harvey et al. ‘922 does not teach or suggest the method of the invention in which specific reagents are required to be added to a test sample. A sample of nucleic acid absorbed on filter paper, as is disclosed by Harvey et al. ‘922, is not a test sample and cannot be used for that purpose.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

III. THE REJECTIONS UNDER 35 U.S.C. § 103(a)

A. The Rejection of Claims 7 and 23 Under 35 U.S.C. § 103(a) as Unpatentable Over Harvey et al. '922

Claims 7 and 23 were rejected under 35 U.S.C. § 103(a) as unpatentable for obviousness over Harvey et al. '922.

To the extent that the amendment of claim 1 and 17 has not obviated this rejection, it is respectfully traversed.

The basis of this rejection is that it would have been obvious to use the device of Harvey et al. '922 treated with sodium perchlorate as a chelator enhancing component because Harvey et al. '922 teaches that sodium perchlorate is a chaotropic agent. Although it may have in fact been *prima facie* obvious to use the device of Harvey et al. '922 treated with sodium perchlorate, this still does not teach the method of the invention. All claim limitations must be considered in evaluating the non-obviousness of an invention in light of prior art. In re Fine, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988). As indicated above, Harvey et al. '922 does not teach the use of these agents in a test sample.

Therefore, even though one of ordinary skill in the art might know that sodium perchlorate is a chaotropic agent, the combination of that knowledge with the teachings of Harvey et al. '922 does not result in the claimed invention. This is because of the lack of teaching of the context of a test sample by Harvey et al. '922. This must be considered in evaluating non-obviousness.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

B. The Rejection of Claim 49 Under 35 U.S.C. § 103(a) as Unpatentable Over Chung et al. (1996) or Sigman et al. '167 or Harvey et al. '922 in View of Ahern et al. (1995)

Claim 49 was rejected under 35 U.S.C. § 103(a) as being unpatentable for obviousness over Chung et al. (1996), Sigman et al. '167, or Harvey et al. '922 (in the alternative) each in view of Ahern, The Scientist 9: 1-5 (1995) ("Ahern (1995)").

To the extent that the amendment of claim 49 has not obviated this rejection, it is respectfully traversed.

Ahern (1995) is cited for the recitation of a kit format. Ahern (1995) does not remedy the deficiencies of the primary references, Chung et al. (1996), Sigman et al. '167, or Harvey et al. '922, which fail to teach suppression of interference by a masking agent in a molecular assay, such as the polymerase chain reaction (PCR) assay. This is because the primary references fail to teach suppression of interference by the specific masking agents recited in this claim as amended.

Accordingly, the combination of Ahern with one or more of the primary references fails to teach or suggest the claimed invention in its entirety. For purposes of assessing patentability of a claimed invention over one or more references in terms of non-obviousness, the invention must be viewed as a whole. Jones v. Hardy, 220 U.S.P.Q. 1021 (Fed. Cir. 1984).

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

VII. THE OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTIONS

A. The Rejection of Claims 1-16 Over Claims 1-8 of Baker '546

Claims 1-16 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,548,546 to Baker ("Baker '546").

To the extent that the amendment to claim 1 has not obviated this rejection, it is respectfully traversed, because claims 1-8 of Baker '546 do not recite a method of suppressing interference by a masking agent in a molecular assay. Preservation of a sample cannot necessarily be equated with suppression of interference by a masking agent, particularly with respect to the specific masking agents recited in claim 1. There can be many purposes for preserving a sample, and a sample can be preserved even though masking agents remain in the sample and would interfere with the performance of an assay such as PCR or hybridization.

In the absence of any evidence that one of ordinary skill in the art would have equated the two, there can be no basis for an obviousness-type double patenting rejection over claims 1-8 of Baker '546. In re Kaplan, 229 U.S.P.Q. 678 (Fed. Cir. 1986); In re Longi, 225 U.S.P.Q. 651 (Fed. Cir. 1985).

C. The Rejection of Claims 17-36 and 48 Over Claims 1-8 of Baker '546 in View of Sigman et al. '167

Claims 17-36 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Sigman et al. '167.

To the extent that the amendment to claim 17 has not obviated this rejection, it is respectfully traversed, essentially for the reasons stated above with regard

to the rejections of claims 1-16 over Baker '546. The obviousness-type double-patenting rejection is considered to be analogous to a prior art rejection under 35 U.S.C. § 103, and there is no teaching of the methods of claim 17-36, even if Baker '546 and Sigman et al. '167 are combined. As demonstrated above, Sigman et al. '167 does not disclose or suggest the suppression of interference by a masking agent or the improvement of a signal response in a molecular assay due to the suppression of interference by a masking agent specifically recited in these claims. Therefore, the combination of Baker '546 and Sigman et al. '167 does not result in the claimed invention, and there is no basis for this obviousness-type double patenting rejection.

D. The Rejection of Claim 49 Over Claims 1-8 of Baker '546 in View of Ahern (1995)

Claim 49 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of Baker '546 in view of Ahern (1995).

To the extent that the amendment to claim 49 has not obviated this rejection, this rejection is also respectfully traversed, essentially for the reasons stated above with regard to the rejections of claims 1-16 over Baker '546 and with regard to the rejections of claims 17-36 over Baker '546 in view of Sigman et al. '167. The obviousness-type double-patenting rejection is again considered to be analogous to a prior art rejection under 35 U.S.C. § 103, and there is no teaching of the kit of claim 49, even if claims 1-8 of Baker '546 and Ahern (1995) are combined. Ahern (1995) is merely cited for the recitation of products in kit format and does not remedy the deficiencies of claims 1-8 of Baker '546 with respect to the failure to teach or suggest suppression of the specific masking agents recited in these claims.

D. The Provisional Rejection of Claim 49 as Unpatentable over Claim 19 Of the '543 Application



Claim 49 was provisionally rejected under the judicially-created doctrine of obviousness-type double patenting over claim 19 of copending Application Serial No. 11/138,543 (“the ‘543 Application”).

This rejection is respectfully traversed.

This rejection is respectfully traversed because there is no teaching or suggestion of the suppression of the specific masking agents recited in claim 49 in claim 19 of the ‘543 Application. As stated above, such obviousness-type double-patenting rejections are again considered to be analogous to a prior art rejection under 35 U.S.C. § 103. The lack of teaching of the specific masking agents recited in this claim means that there is no obviousness-type double patenting.

E. The Provisional Rejection of Claim 49 as Unpatentable over Claims 12-13 and 17-18 of the ‘543 Application in View of Ahern (1995)

Claim 49 was also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-13 and 17-18 of the ‘543 Application in view of Ahern (1995).

To the extent that the amendment of claim 49 has not obviated this rejection, it is respectfully traversed.

This rejection is respectfully traversed because there is no teaching or suggestion of the suppression of the specific masking agents recited in claim 49 in claims 12-13 or 17-18 of the ‘543 Application. As indicated before, Ahern (1995) is cited merely for the possibility of kits, but does not provide the necessary information to create an obviousness-type double patenting situation for this claim. Again, such obviousness-type double-patenting rejections are again considered to be analogous to a prior art rejection under 35 U.S.C. § 103. The lack of teaching of the specific masking agents recited in this claim means that there is no obviousness-type double patenting.

Accordingly, the Examiner is respectfully requested to withdraw this rejection.

Should the only remaining issue be the obviousness-type double patenting rejections, Applicant shall consider the possibility of a terminal disclaimer to advance prosecution. However, this possibility is not to be taken as acquiescence in the obviousness-type double patenting rejections.

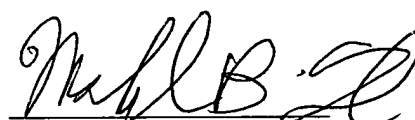
#### VIII. CONCLUSION

In conclusion, all claims remaining for consideration are novel and non-obvious over the references of record, whether considered individually or in combination. These claims are not subject to obviousness-type double patenting. Accordingly, prompt allowance of these claims is requested.

If any issues remain, the Examiner is respectfully requested to telephone the undersigned at (858) 450-0099 x302.

Respectfully submitted,

Date: February 27, 2006



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